Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the January 2003 list were published in the Federal Register in March 2003.

New Approvals

ANADA Number: 200-342

Pioneer Product:	129-831
Trade Name:	Pyrantel Pamoate Paste
Ingredients:	Pyrantel pamoate
Sponsor:	Phoenix Scientific, Inc.
Approval Date:	January 22, 2003
Status:	Over-the-counter
Route:	Oral
Species:	Horses and ponies
Drug Form:	Paste
Concentration:	Each syringe (15.9 milliliters) contains 3.60 grams pyrantel base in 18.8 grams of paste.
Indications:	For the removal and control of mature infections of the following parasites: Large strongyles: *Strongylus vulgaris, S. edentatus, S. equinus* Small strongyles Pinworms: *Oxyuris equi* Large roundworms: *Parascaris equorum*

21CFR 520.2044

NADA Number: 141-201

Trade Name:	Aureomycin® plus Cattlyst®
Ingredients:	Chlortetracycline, laidlomycin propionate potassium
Sponsor:	Alpharma, Inc.
Approval Date:	December 18, 2002
Status:	Over-the-counter
Route:	Oral, via feed
Species:	Cattle (fed in confinement for slaughter)
Drug Form:	Type A Medicated Articles to make two-way combination Type C medicated feeds.
Concentration:	50 – 100 grams of chlortetracycline activity per pound of Type A Medicated Article, 50 grams of laidlomycin propionate potassium activity per pound of Type A Medicated Article.
Indications:	For the treatment of bacterial enteritis caused by *Escherichia coli*; for the control of bacterial pneumonia associated with shipping fever complex caused by *P. multocida* organisms susceptible to chlortetracycline; for the treatment of bacterial pneumonia caused by *P. multocida* organisms; and for improved feed efficiency and increased rate of weight gain.
Tolerance:	*21CFR 556.150* Chlortetracycline: Tolerances are established for the sum of tetracycline residues in tissues of beef cattle, non-lactating dairy cows, and calves of 2 parts per million (ppm) in muscle, 6 ppm in liver, and 12 ppm in fat and kidney. Laidlomycin: Tolerances have not been established.
Withdrawal:	Zero days

21CFR 558.128 & 558.305

Supplemental Approvals

NADA Number: 141-177

This supplemental application provides for the addition of administration in dosage to once daily.

Trade Name:	Mometamax™
Ingredients:	Gentamicin, mometasone, and clotrimazole
Sponsor:	Schering-Plough Animal Health Corp.
Approval Date:	January 9, 2003
Status:	Prescription only
Route:	Topical (otic)
Species:	Dogs
Drug Form:	Liquid (suspension)
Concentration:	Each gram contains 3 milligrams gentamicin, 1 milligram mometasone, and 10 milligrams clotrimazole.
Indications:	For the treatment of otitis externa caused by susceptible strains of yeast (*Malassezia pachydermatis*) and certain bacteria (*Pseudomonas spp.* including *P. aeruginosa*, coagulase positive staphylococci, *Enterococcus faecalis, Proteus mirabilis* and beta-hemolytic streptococci).
Exclusivity:	3 years

21CFR 524.1044h

NADA Number: 107-996

This supplemental application provides for a zero day withdrawal period.

Trade Name:	Avatec® plus BMD®
Ingredients:	Lasalocid sodium, bacitracin methylene disalicylate
Sponsor:	Alpharma, Inc.
Approval Date:	December 4, 2002
Status:	Over-the-counter
Route:	Oral, via feed
Species:	Broiler or fryer chickens
Drug Form:	Type A Medicated Articles to make two-way combination Type C medicated feeds.
Concentration:	Lasalocid sodium - 90.7 grams lasalocid activity per pound Type A medicated article Bacitracin methylene disalicylate – 10 , 25, 30,40, 50, 60 or 75 grams bacitracin activity per pound of Type A Medicated Article.
Indications:	For the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. brunetti, E. mivati,* and *E. maxima,* and for increased rate of weight gain and improved feed efficiency in broiler and fryer chickens.
Tolerance:	*21CFR 556.347* Lasalocid: A tolerance for parent lasalocid (the marker residue) is established as the following: for skin with adhering fat (the target tissue) is 1.2 parts per million, for liver (target tissue) is 0.4 part per million. *21CFR 556.70* Bacitracin: Tolerances for residues of bacitracin in uncooked edible tissues and eggs of chickens are established at 0.5 part per million.
Withdrawal:	Zero days

21CFR 558.311

Actions Taken by FDA Center for Veterinary Medicine

Change of Sponsor Name

From: Vetrepharm Research, Inc.

To: Bioniche Animal Health USA, Inc.
119 Rowe Rd.
Athens, GA 30601
Drug Labeler Code: 064847

From: Bayer Corp., Agricultural Division, Animal Health

To: Bayer Healthcare LLC, Animal Health Division
P.O. Box 390
Shawnee Mission, KS 66201
Dug Labeler Code: 00859

Addition of Patent Number

NADA Number: 141-099

Patent Number: 6,514,951
Expiration Date: February 4, 2020

Suitability Petition Action

Number:	03P-0013/WDL1
Sponsor:	First Priority, Inc.
Petition:	Request permission to withdraw petition to file an ANADA for a generic new animal drug ivermectin which differs from the pioneer product, Eqvalan® (ivermectin) Paste for Horses, Merial Ltd., NADA 134-314, by the following characteristics: The generic product will have a different dosage form (solution) and strength from the pioneer.
Action:	Filed on March 5, 2003.
Number:	03P-0108/CP1
Sponsor:	Cross Vetpharm Group, Ltd.
Petition:	Request permission to file an ANADA for a generic new animal drug apramycin which differs from the pioneer product, Apralan® (apramycin sulfate), Elanco Animal Health, NADA 106-964, by the following characteristic: The generic product will have a different excipient.
Filed:	Filed on March 20, 2003.

Correction of a Final Rule

The Final Rule published in the Federal Register of December 5, 2002 (Green Book update of January 2003) the Food and Drug Administration (FDA) is correcting the range of approved concentrations of decoquinate Type A Medicated Article that may be used to make certain combination Type C medicated feeds for cattle. On page 72372 of the Federal Register, in Section 558.195, in the table in paragraph (e) (2), under the "Decoquinate in grams/ton" column in the entries for (iii), (iv), and (v), "13.6" is amended to read "13.6 to 27.2". This rule is effective March 31, 2003.

Technical Amendment

The Food and Drug Administration has found that the animal drug regulations do not reflect the approved caution statements that must appear on animal feeds containing monensin. The regulation in *21 CFR 558.355* is being amended in paragraph (d) (6) to remove references made to mature turkeys and guinea fowl that were incorporated into the regulations in the Federal Register published on July 26, 2000 (65 FR 45879). This rule is effective March 31, 2003.